

The device was dangerous since in the post partum period and in the acute stages of vaginal infections, treatment as directed would force infective material into or through the cervical canal, resulting in ascending infection with probable serious consequences to the health of the patient.

The device was alleged to be misbranded in the above respects when introduced into, while in, and while held for sale after shipment in, interstate commerce.

**DISPOSITION:** June 19 and September 24, 1951. Default decrees of condemnation. The court ordered that two of the devices be delivered to the Food and Drug Administration and that the remainder be destroyed.

#### NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

3552. TB-1 tables. U. S. v. 4,682 Bottles, etc. (F. D. C. No. 30311. Sample No. 35716-K.)

**LIBEL FILED:** December 8, 1950, Northern District of California; amended libel filed May 31, 1951.

**ALLEGED SHIPMENT:** On or about April 24 and 26, and September 11, 1950, the American Cyanamid Co., Calco Chemical Div., Bound Brook, N. J., shipped to itself in Los Angeles, Calif., a quantity of TB-1 powder. On or about September 15 and 20, 1950, the powder was sold to a firm in San Francisco, Calif., which firm had it tableted and packed into bottles.

**PRODUCT:** 4,682 bottles of *TB-1 tablets* at San Francisco, Calif., together with a number of accompanying leaflets entitled "Reference Manual 601 TB1-PSL The New Antituberculous Drug."

**LABEL, IN PART:** (Bottle) "100 Tablets—1050 TBI-PSL \* \* \* 50 Mgm. Per Tablet."

**NATURE OF CHARGE:** Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

**DISPOSITION:** August 28, 1951. The claimant having indicated that it did not desire to contest the matter, judgment of condemnation was entered and the court ordered that the product be destroyed.

#### DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS\*

3553. Action to enjoin and restrain violations of Section 301 (a) with respect to male and female hormones. U. S. v. Hudson Products Co. (Maywood Pharmacal Co.), and Allen H. Parkinson. Tried to the court. Judgment denying application for permanent injunction reversed upon appeal. (Inj. No. 218.)

**COMPLAINT FILED:** September 29, 1949, Southern District of California, against the Hudson Products Co., a corporation, Long Beach, Calif., also trading under the name of the Maywood Pharmacal Co., at Hollywood, Calif., and against Allen H. Parkinson, president of the Hudson Products Co.

**ALLEGED VIOLATION:** The complaint alleged that the defendants were distributors of certain *male and female hormones*; that the *male hormones* consisted of *methytestosterone tablets* (10 milligrams), *methytestosterone linguets*

\*See also No. 3550.

(5 milligrams), and *methyltestosterone linguets combined with vitamin B<sub>1</sub>*; and that the *female hormones* consisted of tablets containing 0.1 milligram *alpha-estradiol*.

The complaint alleged also that the defendants were violating Section 301 (a) of the Act by causing the introduction into interstate commerce of the 5 milligram *methyltestosterone linguets* and the *methyltestosterone linguets combined with vitamin B<sub>1</sub>*, which were misbranded as follows:

Section 502 (a), the labeling of the linguets was false and misleading since the labeling represented and suggested that the recommended daily dosage was efficacious for use in the treatment of the male hormone deficiency, whereas the recommended daily dosage would be entirely ineffective for such purpose; Section 502 (f) (1), the labeling of the linguets failed to bear adequate directions for use since it failed to state all of the diseases or conditions of the body for which the drug was intended; and Section 502 (f) (2), the labeling of the linguets failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, in such manner and form, as are necessary for the protection of the user since the technical medical terminology in which the cautionary statement on the labeling was couched was inadequate to warn the ordinary lay user that their use may accelerate the malignant growth of the prostate gland or may cause sterility.

It was alleged also with respect to the *methyltestosterone tablets* and the *alpha-estradiol* preparations that the defendants would likely cause the same violations of Section 301 (a) of the Act as they were causing with respect to the linguets since the defendants had sold in the past such products without a physician's prescription and without adequate warnings and since the unrestricted use of *alpha-estradiol* preparations by women may accelerate the malignant growth of cancer of the breast, cervix, and uterus, and may cause injury to the female generative system.

**DISPOSITION:** On January 11, 1950, after a hearing on the issuance of a preliminary injunction, the application for such injunction was denied. The case then was consolidated with that against the El-O-Pathic Pharmacy, et al, reported in notices of judgment on drugs and devices, No. 3550. After the consolidated cases came on for trial before the court on January 31, 1950, judgment was rendered in such cases, denying the Government's application for permanent injunction. Upon appeal, the judgment was reversed and the cases were remanded to the district court for the entry of a decree of permanent injunction in each case.

On July 31, 1951, findings of fact and conclusions of law were filed, supporting the issuance of a permanent injunction, and on the same day an order was entered permanently enjoining the Hudson Products Co., the Maywood Pharmacal Co., and Allen H. Parkinson from violating Section 301 (a) by distributing male or female sex hormone drugs misbranded under Sections 502 (a), 502 (f) (1), or 502 (f) (2).

**3554. Misbranding of Dexedrine Sulfate tablets. U. S. v. Rudolph Matlock (Matlock Pharmacy), and Homer T. Wyatt. Pleas of guilty. Fine of \$1,000 against Defendant Matlock; fine of \$500 against Defendant Wyatt. (F. D. C. No. 30589. Sample Nos. 54198-K, 85883-K, 86036-K to 86038-K, incl.)**

**INFORMATION FILED:** July 17, 1951, Northern District of Texas, against Rudolph Matlock, trading as Matlock Pharmacy, Arlington, Tex., and against Homer T. Wyatt, a pharmacist employed by Rudolph Matlock.